Support for claims 21 and 22 can be found on page 8, line 25 to page 9, line 2 of the specification of the present invention wherein the pellets of the present invention are described as having a different release profile depending on the amount of the insoluble polymer with respect to the amount of soluble polymer. Support for claim 23 which defines that the pellets with a quick release profile and the pellets with a slow release profile are in a ratio between 10:90 and 90:10 can be found on page 8, line 28 of the specification of the present application where the ratio is describe in terms of weight ("in a ratio (i):(ii) by weight) and original claim 23.

In light of the telephone conversation with Examiner Ware on January 22, 2003, Applicants have amended claim 25 to define the layer disposed over the inert nucleus as consisting of an acid labile benzimidazole compound, an inert, non-alkaline polymer soluble in water and one or more pharmaceutically acceptable inert excipients. Support for claim 25 can be found on page 4, lines 4-27 and page 5, lines 15-30 of the specification of the present invention.

U.S. Patent No.'s 5,945,124 and 6,068,856 teach that in order to have a stable formulation of pantoprazole, the active ingredient has to be present in the tablet core or in pellets in the form of its alkaline salts or in direct or intimate mixture with alkaline substances, please see the Examples of U.S. Patent No.'s 5,945,124 and 6,068,856 where pantoprazole is present in the pellets as a sodium salt and/or intimately mixed with alkaline substances.

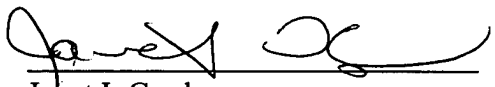
Example 3 of U.S. Patent No.'s 5,945,124 and 6,068,856 describes the starter pellet as including NaOH, and the active pellet is prepared by spraying pantoprazole in the form of sodium salt together with NaOH, see col. 7, line 46 to col. 8, line 8 of U.S. Patent No. 5,945,124 and col. 7, line 36 to col. 8, line 2 of U.S. Patent No. 6,068,856. Example 4 of U.S. Patent No.'s 5,945,124 and 6,068,856 describes the active pellet as being prepared by mixing pantoprazole in the form of sodium salt with sodium carbonate, see col. 8, lines 21-40 of U.S. Patent No. 5,945,124 and col. 8, lines 3-21 of U.S. Patent No. 6,068,856.

This is not required in the present invention. The pellets of the present invention do not have the active compound, any acid labile benzimidazole compound, in direct or intimate contact with any alkaline compound. This is clearly reflected in claim 25 which defines the pellet of present application comprising an acid labile benzimidazole compound, wherein the pellet is defined in part as comprising an inert nucleus and a layer disposed over the inert nucleus consisting of an acid labile benzimidazole compound, an inert, non-alkaline polymer soluble in water and one or more pharmaceutically acceptable inert excipients.

Thus, the pellet comprising an acid labile benzimidazole compound as defined in the claims of the present application does not have the active compound, any acid labile benzimidazole compound, in direct or intimate contact with any alkaline compound. Therefore, Applicants believe the pellet of the present application is patentably distinct over the cited prior art references.

Applicants respectfully submit that the above-made amendment be made of record in the file history of the instant application.

Respectfully submitted,



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CLAIMS

21. (Twice Amended) A composition of modified release [according to claim 20] comprising a mixture of the [wherein the one or more] pellets of claim 25 having [have] the same release profile [of the benzimidazole].

22. (Twice Amended) A composition of modified release [according to claim 20,] comprising a mixture of the [wherein the one or more] pellets of claim 25 having [have] a different release profile [of the benzimidazole].

23. (Twice Amended) A composition of modified release [according to claim 20, further] comprising a mixture of [(i)] the pellets of claim 25 which have (i) [with] a quick release profile and (ii) [pellets with] a slow release profile in a ratio between 10:90 and 90:10 by weight.

25. (Amended) A pellet comprising an acid labile benzimidazole compound, wherein the pellet comprises:

(a) an inert nucleus;

(b) a layer disposed over said inert nucleus (a), consisting of [comprising] an acid labile

benzimidazole compound, an inert, non-alkaline polymer soluble in water and one or more pharmaceutically acceptable inert excipients;

(c) one or more intermediate layers that comprise:

(i) an inert, non-alkaline coating, formed of an inert, non-alkaline polymer soluble in water and one or more pharmaceutically acceptable inert excipients; and

(ii) a system of modified release that comprises an inert, non-alkaline polymer soluble in water and an inert polymer insoluble in water;

said intermediate layer(s) (c) disposed over said layer (b) that covers the inert nucleus; and

(d) an external layer comprising an enteric coating disposed over said intermediate layer(s) (c).